

REMARKS:

The Office Action dated June 24, 2003 has been carefully considered, as have newly cited references Shchervinsky, Patent No. 6,126,675, and Frassica, Patent No. 5,989,230.

Claims 39 and 60 have been amended in a manner which is believed to patentably distinguish them from the Shchervinsky and Frassica references. More specifically, claims 39 and 60 have been amended to recite an opening in the proximal region of the elongate shaft (opening 140 in Fig. 3) and an opening in the distal region of the plug, such opening also being shown in Fig. 3 and being described in the specification from page 13, line 16, through page 15, line 2. The claims have also been amended to recite that the lumen 138 which runs through the elongate shaft and the plug connects the opening in the distal region of the plug to the opening in the proximal region of the elongate shaft. The purpose of these openings and the lumen connecting them is, as described at pages 13-15 of the specification, to permit blood flow through the lumen. Furthermore, the purpose of permitting this blood flow is one of providing an indication that the distal region of the plug has reached the lumen of a blood vessel, thereby providing an indication of the location of the distal region of the plug.

Thus, to restate, claims 39 and 60, as now amended, recite a device in which there is a lumen which permits flow between the opening in the plug and the opening in the elongate shaft. Claims 39 and 60 also recite that the subject matter of the claims is an "apparatus for sealing a passage through tissue". We now turn to a discussion of the newly cited prior art upon which claims 39-44, 52-55, 60-63, and 65-68 have been rejected. These claims have been rejected as

anticipated by Shchervinsky. However, a key element of Shchervinsky is flat pivotal closure 26 which is at the distal end of device 20 which the Examiner has characterized as an elongate shaft. Applicant acknowledges that the Shchervinsky patent discloses a device for sealing puncture wounds in blood vessels and that the device of Shchervinsky has an open proximal end and a lumen which connects with the open proximal end. However, the distal end of the device of Shchervinsky does not have an opening in it, as recited in the claims, as amended. Rather, the distal end of Shchervinsky's device is provided with "closure 26" which prevents the passage of a fluid either into or out of the distal end of the Shchervinsky device. As disclosed in Shchervinsky, the very purpose of the device is to create a closed chamber in which a gas or liquid can be caused to expand. The entire purpose of Shchervinsky would be defeated if the distal end of his device contained an opening as recited in the claims. Indeed, if such an opening existed, use of the Shchervinsky device as described would result in pumping a foreign material into the blood vessel of the patient, a highly undesirable situation.

Furthermore, as disclosed at pages 13-15 of the present application, the purpose of the lumen in Applicant's device is to permit blood flow from the distal region of the device to the proximal region of the device so as to provide a location indication. Shchervinsky, on the other hand, as disclosed at column 5, lines 6-10, uses a radio opaque material to determine the location of the distal end of his device.

Thus, both the structure and the purpose of Applicant's device and the device of Shchervinsky are fundamentally different. In fact, the function of the respective devices is

diametrically opposed, i.e., the structure of Applicant's device permits blood flow from the distal region to the proximal region of the device, whereas the structure of Shchervinsky's device prevents such flow. Accordingly, Shchervinsky cannot be considered to be an anticipation of the claims rejected over it.

Turning now to the rejection of claim 82 over Frassica, it is respectfully submitted that the device of Fig. 31A of Frassica is entirely remote from the apparatus of the present application. As stated at column 21, lines 48-63, the device of Fig. 31A is a "camera introducer catheter" which has a "window 511 on the distal end of the tip 501." Thus, the device of Frassica:

1. Has a closed distal end and does not have an opening in its distal region as recited in the claims of this application.
2. Is directed to a camera introducer catheter, not an apparatus for sealing a passage through tissue, as recited in the present claims.
3. Does not have a lumen which permits flow of fluid into one end of the device and out of the other end of the device.

Applicant further notes that Figs. 13, 14 and 15 are described as illustrating dilator 201 and occluders 211 and 221. Neither the dilator nor the occluders are disclosed as having an opening at one end and an opening at the other end and a lumen which connects the openings. Thus, the dilator and occluders disclosed by Frassica also do not meet the terms of claim 82, as amended.

In summary, with regard to the rejected claims, it is believed that the present amendments to the claims render them patentable over the cited prior art. In addition, many of the dependent claims recite features, e.g., the hemostasis-promoting material and infection-resistant material of claim 44, a seal for selectively sealing the lumen in the elongate shaft of claims 54 and 55, the cavity of claim 62, and hemostasis-promoting material and infection-resistant material of claims 63 and 65, and the seal for selectively sealing the lumen of claim 67. The Shchervinsky patent does not disclose any of these features. In this regard, it is respectfully pointed out that, contrary to the Examiner's statement in the Office Action with regard to claims 54 and 67, the end of syringe 30 of Shchervinsky does not selectively seal the lumen 20. The word "selectively" means that the recited seal can be opened or closed at any time elected by the operator at any stage of use of the device. In contrast, no such options are available with regard to use of the syringe 30 of Shchervinsky. Rather, the syringe 30 contains a filler 32 which is forced into device 20 and causes the expandable section 28 to expand, as stated at column 5, lines 21-23, of Shchervinsky. After this is done, clip 41 or check valve 50 are installed to permanently seal the lumen. Thus, the syringe 30 does not perform a sealing function, but rather a filling function and the lumen is then permanently sealed. There is no selectivity of any sort available to the user of the Shchervinsky device with regard to sealing the proximal end of the lumen.

With regard to claims 45-47, 64 and 80, which the Examiner has withdrawn from consideration, it is respectfully pointed out that claim 39 is generic to claims 45-47, 64 and 80.

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Thus, if claim 39 is allowed, it is believed that Applicant is entitled to an examination of claims 45-47, 64 and 80 in the present application.

It is believed that this application is in condition for allowance. Thus, a favorable action is respectfully solicited.

Respectfully submitted,

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